

OCT 31 2013

510(k) Summary

per 21 CFR §807.92

Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311		
Contact Name and Information	Carol Tiffany Regulatory Affairs Specialist Phone: 763-494-1106 Fax: 763-494-2222 e-mail: carol.tiffany@bsci.com		
Date Prepared	20 September 2013		
Proprietary Name	OffRoad™ Re-Entry Catheter System		
Common Name	Percutaneous Catheter		
Product Code	PDU – Catheter for Crossing Total Occlusions		
Classification	Class II, 21 CFR Part 870.1250 – Percutaneous Catheter		
Predicate Device	Cordis Outback Re-Entry Catheter	K083814	January 13, 2009
Device Description	The OffRoad Re-Entry Catheter System consists of two components; the OffRoad Positioning Balloon Catheter and the OffRoad Micro-Catheter Lancet. Together they assist in accessing the true lumen after bypassing a chronic total occlusion lesion in the peripheral vasculature.		
Intended Use/ Indications for Use of Device	The OffRoad Re-Entry Catheter System is intended to facilitate the placement and positioning of guidewires within the peripheral vasculature beyond stenotic lesions, including sub and chronic total occlusions.		
Comparison of Technological Characteristics	The OffRoad Re-Entry Catheter System is substantially equivalent to the Cordis Outback Re-Entry Catheter (K083814) (the Predicate Device) that the Food and Drug Administration (FDA) has already cleared for use to facilitate placement and positioning of guidewires and catheters within the peripheral vasculature. The OffRoad Re-Entry Catheter System and the predicate device have the same intended use and similar indications, technological characteristics, and principles of operation. The minor technological differences between the OffRoad Re-Entry Catheter System and its predicate device do not raise any new issues of safety or effectiveness.		
Performance Data	Currently no FDA mandated or voluntary performance standards exist for this device. Bench testing, biocompatibility testing, and pre-clinical animal testing were performed to support a determination of substantial equivalence. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during the testing and, therefore, these devices may be considered substantially equivalent to the predicate devices.		

The following biocompatibility and bench testing were completed on the OffRoad™ Re-Entry Catheter System:

Biocompatibility

MEM Elution Cytotoxicity	Hemolysis (Direct Contact)
Sensitization	Ames Mutagenicity
Intracutaneous Reactivity	Mouse Lymphoma
Acute Systemic Toxicity	Coagulation
Materials Mediated Pyrogenicity	In Vitro Hemocompatibility
USP Physicochemical	Partial Thromboplastin Time
Complement Activation	Natural Rubber Latex

The following in-vitro performance tests were completed on the OffRoad™ Re-Entry Catheter System:

Bench

Tensile Strength	Shaft Outer Diameter (OD)
Catheter Effective Length	Shaft to Y-Connector Tensile Strength
Deflation Time	Balloon Nominal Diameter
Balloon Rated Burst Pressure (RBP)	Proximal Balloon Bond Tensile Strength
Balloon Repeat Inflation	Corrosion
Surface Finish and Cleanliness	Guidewire Compatibility
Balloon Catheter/Micro Catheter Compatibility	Sheath Compatibility
Flexibility and Kink	Simulated Use and Coating Integrity
Particulate Evaluation	Torque after Conditioning

Pre-Clinical Animal Testing

BSC conducted a Preclinical study in naïve peripheral arteries of six common swine to evaluate the acute performance of the OffRoad™ Re-entry Catheter System in comparison to the predicate Cordis OUTBACK® LTD Re-Entry Catheter.

Devices	Evaluation Criteria	OffRoad Testing Summary
OffRoad™ Re-entry Catheter N=7	<p>Pass all required performance criteria during use:</p> <ul style="list-style-type: none"> • Device preparation • Support product compatibility • Proper positioning and use of Re-entry device 	<p>OffRoad received passing ratings for all performance criteria.</p> <ul style="list-style-type: none"> • Device preparation was rated acceptable in all cases • Compatibility with all support product was rated acceptable • Positioning and use was rated acceptable in all cases
Cordis OUTBACK® LTD™ Re-Entry Catheter N=5	<ul style="list-style-type: none"> • Confirm re-entry • Withdrawal after use <p>Histological characterization, and comparison of vessel wall effects after use of devices</p>	<ul style="list-style-type: none"> • Re-entry was confirmed with all devices. • Withdrawal of all devices was rated acceptable • Two instances of small arterial wall perforations associated with very limited perivascular hemorrhage near the site of re-entry were observed. Based on the data collected, neither perforation was considered a safety concern by the Study Pathologist and Study Director.

Study Results Conclusion:

OffRoad and Outback devices met all protocol-specified evaluation criteria, and were used successfully to gain re-entry into the true lumen from within a vascular subintimal track created in the porcine naïve peripheral artery model. Vascular effects attributed to re-entry procedures using OffRoad and Outback devices were similar.

Two instances of arterial wall perforations near the site of re-entry were observed, and were not considered a safety concern. This is based on the small size, limited perivascular hemorrhage, aggressive study procedures, which required creation of a subintimal track using a wire prior to any re-entry device use, and the fact that porcine non-diseased peripheral vessels are thinner than human diseased peripheral arteries.^{1, 2}

Results from the study support safety of the OffRoad™ Re-entry Catheter System during clinical use in the peripheral vasculature.

References

1. Sarkola T, Transcutaneous very-high resolution ultrasound to quantify arterial wall layers of muscular and elastic arteries: Validation of a method. Atherosclerosis. 2010 Oct; 212(2); 516-23
2. Wong M et al, Ultrasonic – Pathological Comparison of the Human Arterial Wall Arterioscler Thromb Vasc Biol. 1993; 13;482-486

Performance Data – Clinical

A prospective clinical study of 92 subjects was conducted at 12 investigational sites to provide additional clinical data regarding the safety and technical success of the OffRoad Re-Entry Catheter System for subintimal recanalization of chronic total occlusion (CTO) in the femoropopliteal arteries (Re-ROUTE, NCT01500031).

Study Subjects

Study subjects were required to have claudication or critical limb ischemia (Rutherford Category 2-5) and a de novo or re-occluded CTO (99-100%) lesion in a native femoropopliteal artery.

Study Endpoints

The primary safety endpoint was a composite rate of major adverse events (MAEs) related to the OffRoad System through 30 days post index procedure including: death, perforation requiring intervention, clinically significant peripheral embolism, and major amputation (amputation of the treated lower limb at the ankle level or above).
The primary effectiveness endpoint was device technical success, defined as the placement of a guidewire in the true lumen distal to a CTO as confirmed by the angiography core lab.

Clinical Study Results

The composite rate of major adverse events (MAEs) related to the OffRoad System at 30 days was 3.3%. The single sample z-approximation one-sided 95% upper confidence bound was 6.5%, which was less than the threshold value of 15%, thus, the primary safety endpoint has been met. The site-reported device technical success rate was 84.8%. The single sample z-approximation one-sided 95% lower confidence bound was 79%, which was greater than the threshold value of 76%, thus, the primary effectiveness endpoint has been met. The primary safety and effectiveness endpoint results are summarized in Table 1.

Table 1 Primary Endpoints - Subjects: N=92

Characteristics	Overall	95% CI	Non-Inferiority Analysis	
Safety (at 30-Day)			Upper 1-Sided 95% CI	Performance goal (PG)
MAE (Device-related)	3.3% (3/90)	[0.0%, 7.0%]	6.5% ^b	15%
Death	0.0% (0/90)	[0.0%, 0.0%]		
Perforation requiring intervention	0.0% (0/90)	[0.0%, 0.0%]		
Clinically significant peripheral embolism	3.3% (3/90)	[0.0%, 7.0%]		
Major amputation at ankle level or above	0.0% (0/90)	[0.0%, 0.0%]		
MAE (Regardless of relatedness to device)	7.8% (7/90)	[2.2%, 23.3%]		
Death	1.1% (1/90)	[0.0%, 3.3%]		
Perforation requiring intervention	1.1% (1/90)	[0.0%, 3.3%]		
Clinically significant peripheral embolism	5.6% (5/90)	[0.8%, 10.3%]		
Major amputation at ankle level or above	0.0% (0/90)	[0.0%, 0.0%]		
Effectiveness (On the day of Procedure)			Lower 1-Sided 95% CI	PG
Device Technical Success ^a				
Site Reported	84.8% (78/92)	[77.4%, 92.1%]	78.6% ^c	76%
Core Lab Confirmed	92.1% (70/76)	[86.0%, 98.2%]	87.0%	76%

Numbers are % (Count/Sample Size)

Denominators are based on 1) subjects with events, and 2) subjects with no events but have been enrolled at least 23 days.

^a Device Technical Success rate, defined as placement of a guidewire in the true lumen distal to a CTO as confirmed by angiography core lab.

^b Event rate was lower than the pre-specified acceptable threshold

^c Technical success rates exceeded the pre-specified performance goal

Events are based on CEC data.

Abbreviations: MAE= major adverse event, PG= performance goal, CEC= Clinical Event Committee

Clinical Study Conclusion	The Re-ROUTE results are consistent with published data on other re-entry devices. The results of the Re-ROUTE study support the safety and performance of the OffRoad Re-Entry Catheter System and the determination of substantial equivalence.
Conclusion	Based on the indications for use, technological characteristics, safety and performance testing, pre-clinical studies, and the Re-ROUTE clinical study, the OffRoad Re-Entry Catheter System has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the Cordis Outback Re-Entry Catheter, K083814.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

October 31, 2013

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Boston Scientific Corporation
c/o Ms. Carol Tiffany
Senior Regulatory Affairs Specialist
One Scimed Place
Maple Grove, MN 55311-1566

Re: K131914

Trade/Device Name: OffRoad™ Re-Entry Catheter System
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU
Dated: September 25, 2013
Received: September 26, 2013

Dear Ms. Tiffany:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131914

Device Name: OffRoad™ Re-Entry Catheter System

Indications for Use:

The OffRoad Re-Entry Catheter System is intended to facilitate the placement and positioning of guidewires within the peripheral vasculature beyond stenotic lesions, including sub and chronic total occlusions.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman -S
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